Summary of Safety and Effectiveness for the Reprocessed Electrosurgical Instruments

submitted by

SISS Inc. (d.b.a. MediSISS)
P.O. 2060
723 Curtis Court
Sisters, OR 97759
Phone: (800)-860-9482
Fax: (541) 549-4527
Email: mabarker@MediSISS.com

Contact Person: Mary Ann Barker
Device Trade Names: Reprocessed Electrosurgical Instruments
Common Names: Reprocessed Electrosurgical Instruments
Classification Names: Electrosurgical cutting and coagulation device and accessories. CFR §876.4300

Identification of a Legally Marketed Predicate Device

The SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments are substantially equivalent to the electrosurgical instruments manufactured by:

Circon/ACMI
Weck (Pilling Surgical)

These devices are legally marketed and distributed pursuant to 510(k)'s K884306, K932293, and K965176 and the counterpart devices from the original manufacturers.

They are also similar to the reprocessed electrosurgical instruments and accessories reprocessed by Alliance Corporation and legally marketed and distributed pursuant to 510(k)'s K012608, K012638, K012603. Likewise, Adven Medical, Inc *Reprocessed Used Disposable Endoscopic Scissors and Graspers* - 510(k) K012696; SterilMed, Inc. *Reprocessed Laparoscopic Electric Instruments*: - 510(k) K012598; Vanguard Medical Concepts, Inc *Vanguard Reprocessed Endoscopic Instruments*, 510(k) K012700; and SISS, Inc *Electrosurgical Electrodes* – 510(k) K012669.

Device Description

Reprocessed Electrosurgical Instruments may consist of hand-manipulated devices with electrocautery capability and with or without rotation capability.

The handpiece handles are connected to the distal end-effector by a narrow-diameter insulated barrel or shaft. The distal end of the device consists of a variety of distal end configurations including: dissectors (straight or curved), graspers, scissors (curved, hooked, or metzenbaum), shears, and cutting or dissecting forceps. The devices may be monopolar, bipolar, or tripolar. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula.

If the instrument has a scissor or jaw end-effector these are opened and closed using the handles. The device's insulated shaft may be designed to (depending on the device model and type) be rotated (up to 360°) either direction (using a knob on the handle.) The jaws of some models may be rotated by manipulating controls on the handpiece. Grasper and clamp models may have manipulating jaws operated at the handpiece to lock and hold tissue.

Intended Use

The SISS Inc. (d.b.a. MediSISS) Reprocessed electrosurgical instruments have applications in a variety of minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, and/or to facilitate coagulation, transection, resection, mobilization, and dissections of tissue.

Summary of Technological Characteristics

The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed devices(s) and the predicate device(s) have the same materials and product design. There are no changes to the claims, intended use, clinical applications, patient populations, performance specifications, or methods of operation. The technological characteristics of the reprocessed electrosurgical devices are the same as those of the legally marketed predicate devices. The technological characteristics of the reprocessed electrosurgical device(s) are the same as those of the legally marketed predicate devices. In addition the MediSISS™ manufacturing process includes 100 % visual and mechanical testing of all products prior to packaging, labeling, and sterilization.

Summary of Performance Data

The SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments comply with the following standards, practices, and guidance's:

- ANSI/AAMI/ISO 11135-1994, *Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization*
- ANSI/AAMI/ISO 10993-7:1995, *Biological Evaluation of Medical Devices—Part 7: Ethylene oxide sterilization residuals*

- ANSI/AAMI/ISO 10993-1: 1997 (1999 Edition). *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.*

Cleaning, sterilization, packaging validations, and visual/mechanical testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

MediSISS™ Reprocessed Electrosurgical Instruments undergo mechanical testing to demonstrate that the parts do not change in function. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging.

Cleaning, sterilization, and packaging validations, functional/performance testing, (product certification,) and (biocompatibility) testing (or certification of the replacement insulation material) demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Representative samples of reprocessed electrosurgical instruments underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

The SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments are substantially equivalent to the identified predicate devices. This has been demonstrated through bench testing and comparative analysis of features.

Conclusion

Since the Reprocessed Electrosurgical Instruments meet the requirements of the stated standards and embody technological characteristics identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Reprocessed Electrosurgical Instruments will be reprocessed per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

In accordance with the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket notification, SISS Inc. (d.b.a. MediSISS) concludes that the modified devices (Reprocessed Electrosurgical Instruments) are safe, effective and substantially equivalent to the predicate devices described herein.

Based on the information provided herein, the 510(k) "Substantial Equivalence" Decision Making Process Chart, and the FDA – "510(k) Guidance Document for General Surgical Electrosurgical Devices" 5/10/95, we conclude that the SISS Inc. (d.b.a. MediSISS) reprocessed electrosurgical instruments are substantially equivalent to the predicate devices under the Federal Food and Drug, and Cosmetic Act.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2003

Siss, Inc. (d.b.a. MediSiSS™)
Mr. Marc M. Mouser
Project Engineer, Medical Devices
FDA Office Coordinator
UL Conformity Assessment Services
Underwriters Laboratory, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K030919
Trade/Device Name: See Attachment
Regulation Number: 876.4300
Regulation Name: Reprocessed Endoscopic Electrosurgical Unit (with or without Accessories)
Regulatory Class: II
Product Code: NLR
Dated: June 16, 2003
Received: June 20, 2003

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K030919 Premarket Notification of MediSISS Reprocessed Electrosurgical Devices

Device	Manufacturer	Model No.
Dolphin Nose Dissector	Weck (Pilling Surgical)	722420a
Maryland Dissector	Weck (Pilling Surgical)	722425a
Straight Dissector	Weck (Pilling Surgical)	725401a
Fenestrated Dissector	Weck (Pilling Surgical)	725430a
Mixter Dissector 90° angle	Weck (Pilling Surgical)	727210a
Mixter Dissector 45° angle	Weck (Pilling Surgical)	727211a
Maryland Dissector	Weck (Pilling Surgical)	727425a
Cone Tip Dissector with spoon	Weck (Pilling Surgical)	725405a
Dolphin Nose Dissector	Weck (Pilling Surgical)	725420a
Maryland Dissector	Weck (Pilling Surgical)	725425a
Tri-polar Cutting Forceps, 10 mm, 32 cm	Circon ACMI	006689-901
Tri-polar Cutting Forceps w/rotation, 10 mm, 32 cm	Circon ACMI	006689-903
Tri-polar Cutting Forceps for open procedures, 10 mm, 15 cm	Circon ACMI	008140-901
Tri-polar Cutting Forceps, 5 mm, 32 cm	Circon ACMI	008593-901

Indications for Use

Page 1 of 1

510(k) Number (if known):_____

Device Name: SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments and Accessories.

Indications for Use:

The SISS Inc. (d.b.a. MediSISS) Reprocessed electrosurgical instruments have applications in a variety of minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, and/or to facilitate coagulation, transection, resection, mobilization, and dissections of tissue.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030919